

Citation:

Sandora TJ, Shih MC, Goldmann DA. Reducing absenteeism from gastrointestinal and respiratory illness in elementary school students: A randomized, controlled trial of an infection-control intervention. *Pediatrics*. 2008 Jun; 121(6): e1,555-e1,562.

PubMed ID: [18519460](#)

Study Design:

Randomized controlled trial

Class:

A - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

Assess the effectiveness of a multi-factorial infection-control intervention, including alcohol-based hand sanitizer and surface disinfection, in reducing absenteeism caused by gastrointestinal and respiratory illnesses among elementary school students.

Inclusion Criteria:

- Attending either grades three, four or five at a single elementary school in Avon, Ohio
- Teachers agreed to participate
- Student agreed to participate
- Parent or guardian gave consent.

Exclusion Criteria:

- Refused to participate
- No contact made.

Description of Study Protocol:**Recruitment**

- School selected because of classroom arrangement that supported study design
- Written recruitment letter cosigned by classroom teacher was distributed to families of eligible students (grades three to five).

Design

- Clustered randomization was used to assign classroom teams to the intervention or control

groups

- Randomization was stratified by team size (grades four and five teams were larger than grade three, so each group contained one larger and two smaller teams)
- Children and teachers used hand sanitizer and surface disinfection, respectively
- Swabs of surfaces were taken by teachers and cultured by researchers
- Number and reason for absences was recorded.

Blinding Used

Staff-recorded absences and reason for absences were blinded.

Intervention

- Teachers disinfected students' desks once daily after lunch using 0.29% quaternary ammonium chloride compound wipes. Teachers were instructed on proper usage
- Students were instructed on proper usage of alcohol-based hand sanitizer and encouraged to use it before and after lunch, after using the restroom on return to the classroom (hand washing with soap and water occurred in the bathroom because hand sanitizers weren't placed there) and after any contact with potentially infectious secretions (e.g., sharing toys that had been mouthed, exposure to ill children). A sanitizer was located in each classroom.

Statistical Analysis

- Absenteeism rates (number of ill days per student) were modeled as Poisson variables
- Generalized estimating equations were used to compare absenteeism rates between intervention and control groups, accounting for potential correlations among students on the same team. Comparison was first performed in an unadjusted analysis and was then adjusted (using multivariable regression models) for potential confounders (including gender, race, health status, family size and hand sanitizer use in the home)
- Bacterial counts on classroom surfaces were compared between intervention and control groups using Wilcoxon rank-sum tests
- The presence of virus on classroom surfaces was compared between intervention and control groups using Fisher's exact test
- Statistical analyses were performed using SAS 9.1
- Two-sided P-values of <0.05 indicated statistical significance
- Sample size was fixed based on the number of students available in the participating classrooms. Power was then calculated based on this sample size.

Data Collection Summary:

Timing of Measurements

- *Absences:*
 - Student absences were recorded over an eight-week period (March to May 2006) in the usual fashion by the school employee (blinded) who normally answers this dedicated phone line. Existing policy requires a parent to call to report absences
 - Data collected included student name, date of absence and reason for absence
 - Absences were classified as respiratory or GI-related according to standard definitions as follows:
 - *Respiratory:* Acute illness that included one or more of the following symptoms:
 - Runny nose

- Stuffy or blocked nose
- Fever or chills
- Sore throat
- Sneezing
- *GI*: Acute illness that included two or more of the following symptoms:
 - Watery or much-looser-than-normal bowel movements and stools over a 24-hour period
 - Vomiting
- *Swabs for bacteria and viruses from classroom surfaces*:
 - Teachers were trained on how to collect surface samples. Samples were analyzed by the University of Arizona, chosen for its experience in processing swabs from environmental surfaces for viral pathogens
 - Swabs for bacteria and viruses from three classroom surfaces (desktops, computer mice and water fountain) were obtained once per week during the first five study weeks
 - Four desktops were selected at random and sampled each week
 - One water fountain and two computer mice in each classroom were sampled weekly.

Dependent Variables

- Student absences for GI and respiratory illness (number of ill days per student)
- Bacterial colony counts from designated classroom surfaces were measured as median total heterotrophic bacterial count in colony-forming units (CFUs)
- Presence of selected viruses on classroom surfaces were measured as presence of four viruses (parainfluenza virus 3, influenza A, respiratory syncytial virus and norovirus) as detected by reverse-transcription polymerase chain reaction.

Independent Variables

- Student use of alcohol-based hand sanitizer
- Teacher use of quaternary ammonium wipes to disinfect classroom surfaces.

Control Variables

- Gender
- Race
- Health status
- Family size
- Hand sanitizer use in the home.

Description of Actual Data Sample:

- *Initial N*: 363 eligible; 78 excluded (63 refused to participate; 15 no contact made)
- *Attrition (final N)*: 285 randomly assigned
- *Age*: Grades 3-5
- *Ethnicity* (Numbers may not sum to group totals for all of the variables, because of missing responses):
 - White: N (%) = Control Families (N=144): 125 (87%); Intervention Families (N=146): 130 (90%)
 - Black: N (%) = Control Families (N=144): 4 (3%); Intervention Families (N=146): 1

(1%)

- Other: N (%) = Control Families (N=144): 13 (9%); Intervention Families (N=146): 10 (0%)

- *Other relevant demographics:*

Demographic Variable	Control (N=144 Families) ^a	Intervention (N=146 Families) ^a	p ^b
Gender, N (%)			0.64
Male	70 (49)	65 (45)	
Female	74 (51)	79 (55)	
Number of people currently living in home, N (%)			0.83
Three or less	22 (15)	17 (12)	
Four to five	96 (67)	109 (75)	
Six or more	26 (18)	19 (13)	
Household member health status, N (%)			0.09
Excellent	80 (56)	97 (67)	
Very good	55 (38)	40 (28)	
Good	8 (6)	8 (6)	
Fair	1 (1)	0 (0)	
Poor	0 (0)	0 (0)	
Current hand-sanitizer use in home, N (%)			0.81
Yes	68 (47)	70 (49)	
No	76 (53)	73 (51)	

^aNumbers may not sum to group totals for all of the variables because of missing responses.

^bData from the Fisher's exact test or Cochran-Armitage trend test.

- *Location:* Avon, Ohio.

Summary of Results:

Key Findings

- Compared with the control group, the unadjusted absenteeism rate for GI illness was significantly lower in the intervention group [RR: 0.86 (95% CI: 0.79 to 0.94); P < 0.01]
- After adjusting for race, health status, family size and current hand-sanitizer use in the home, the absenteeism rate for GI illness remained significantly lower in the intervention group compared with the control group [RR: 0.91 (95% CI: 0.87 to 0.94); P < 0.01]

- Norovirus was the only virus detected on classroom surfaces during the study. Norovirus was detected on significantly fewer surfaces in the intervention classrooms when compared with controls (9% of intervention classroom samples were positive vs. 29% of control samples; $P < 0.01$)
- The median bacterial colony count on classroom surfaces was 60 CFU per ml in the control group and 50 CFU per ml in the intervention group ($P = 0.11$).

Author Conclusion:

- A multifaceted intervention that included alcohol-based hand sanitizer use and disinfection of classroom surfaces reduced absenteeism for GI illness among elementary school students
- The intervention did not impact absenteeism from respiratory illness
- Norovirus was detected less frequently in intervention classrooms.

Reviewer Comments:

The authors note the following limitations:

- *This research cannot prove that the demonstrated reduction in norovirus exposure was the cause of decrease in absenteeism from GI illness; it's possible that other GI pathogens were contributors*
- *Because the study design was not factorial, authors could not determine the relative contributions of hand hygiene and surface disinfection to achieving a reduction in absenteeism from GI illness*
- *Illness definitions were symptom-based, not microbiologically confirmed, so misclassification is possible.*
- *Authors did not verify parental reporting of reason for absence, although there's no reason to believe misclassification would be different between intervention and control groups*
- *No diagnostic tests were performed, so the authors cannot definitively state that the observed reduction in absenteeism is linked to the observed reduction in environmental pathogens*
- *The authors did not directly observe usage patterns, and cannot address timing of usage in relation to specific exposures*
- *The study took place in a single school, so results may not be generalizable.*

Reviewer comments:

- *It is unclear how this particular elementary school was recruited, although authors state the classroom set-up fit well with the study design*
- *Other hand washing that may have resulted from hygiene instruction was not measured*
- *Patient compliance was only measured by collection of empty containers.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	Was the research question clearly stated?	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	Was the selection of study subjects/patients free from bias?	???
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	Were study groups comparable?	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method of handling withdrawals described?	N/A
4.1.	Were follow-up methods described and the same for all groups?	N/A
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	N/A
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blinding used to prevent introduction of bias?	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	???

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcomes clearly defined and the measurements valid and reliable?	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	???
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclusions supported by results with biases and limitations taken into consideration?	Yes
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due to study's funding or sponsorship unlikely?	No
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	No